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CLINICAL TRIAL REPORT

Migu Capsules in the Treatment of Osteoporotic Low Back Pain in Postmenopausal Women: A Single-Center Randomized Controlled Trial

Chen-Ming Tang[1,2,*], Yuan-Chuan Chen[1,2,*], Yu-Cheng Huang[1,2], Yuan Meng[1,2], Jing-Chun Xia[1,2], Jian Pang[1,2], Ying Shi[1,2]

[1]Shi's Center of Orthopedics and Traumatology, Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China; [2]Institute of Traumatology & Orthopedics, Shanghai Academy of Traditional Chinese Medicine, Shanghai, People's Republic of China

*These authors contributed equally to this work

Correspondence: Jian Pang; Ying Shi, Shi's Center of Orthopedics and Traumatology, Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai, People's Republic of China, Email pangjian@shutcm.edu.cn; shiying1974@126.com

Purpose: This trial aimed to investigate the efficacy of Migu capsules in treating osteoporotic low back pain.

Patients and Methods: In this single-center trial, we randomly assigned patients with osteoporotic low back pain that had lasted for 3 months in a 1:1 ratio to receive Migu capsules alongside Caltrate D in treatment group or to receive Caltrate D only in control group, both for 48 weeks. The primary outcome measure was the intensity of low back pain on a visual analog scale at 24 weeks after enrollment. Secondary outcome measures included the Roland-Morris Disability Questionnaire (RMDQ), bone turnover markers, and bone mineral density.

Results: A total of 100 patients were enrolled, with 50 in each group. At baseline, the mean score for low back pain intensity was 6.2 in the treatment group and 6.1 in the control group. The primary outcome of the low back pain intensity score at 24 weeks was 2.9 in the treatment group and 4.7 in the control group (adjusted mean difference, −1.8; 95% confidence interval, −2.3 to −1.4; $P<0.001$). Secondary outcomes including the score on RMDQ and pain at 48 weeks were in the same direction as the primary outcome. Compared to the control group, the treatment group only showed a difference in bone density after continuous intervention for 48 weeks ($P<0.05$). Three patients experienced a mild adverse event associated with the intake of Migu capsules.

Conclusion: Migu capsules can alleviate bone pain and reduce functional disabilities caused by osteoporotic lower back pain.

Keywords: osteoporotic low back pain, traditional Chinese medicine, osteoporosis, low back pain, Migu capsules

Introduction

Low back pain, a prevalent issue among a significant portion of the elderly population, ranks as one of the five major musculoskeletal disorders in China, according to the 2017 Global Burden of Disease.[1] Increasing evidence suggests that a subset of individuals with low back pain also suffers from osteoporosis.[2–6] Termed "osteoporotic low back pain", this condition is characterized by patients experiencing both low back pain and osteoporosis without acute vertebral fractures.[5,6] Individuals in this group not only endure a diminished quality of life due to low back pain but also face an elevated risk of fracture associated with osteoporosis.[7,8] Moreover, in line with guidelines released by the National Medical Products Administration in 2015, individuals experiencing bone pain attributed to osteoporosis are currently identified as a population of concern, necessitating urgent effective intervention measures.[9]

In Traditional Chinese Medicine (TCM) theory, patients with osteoporotic low back pain exhibit characteristics associated with both "Bone flaccidity" and "Bone impediment", often categorized with a "kidney deficiency pattern" in TCM pattern differentiation.[10] A multicenter randomized controlled trial conducted by Zihao Qin and colleagues demonstrated that applying the treatment principle of "benefiting qi and tonifying kidney yin and yang" could alleviate

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osteopenic low back pain.[11] Migu capsules, formulated by renowned TCM practitioner Shi Yin Yu, specifically target osteoporosis and related symptoms, focusing on the pattern differentiation of "deficiency of the liver and kidney".[12,13] The Migu capsule has obtained an invention patent from the Chinese National Intellectual Property Administration (Application No. CN201110442673). Previous randomized controlled trials have shown that a six-month course of Migu capsules can help maintain bone mineral density in the vertebrae and femoral neck while improving clinical symptoms associated with the deficiency of the liver and kidney pattern in patients with osteoporosis.[12,13] However, whether Migu capsules can alleviate osteoporotic low back pain remains unknown. Hence, our aim was to determine the efficacy of Migu capsules for osteoporotic low back pain at 24 weeks by conducting a single-center randomized controlled trial. We hypothesize that the combination of Migu Capsules with Caltrate D at 24 weeks is superior to Caltrate D alone in terms of pain relief.

Material and Methods

Clinical Data

From July 2019 through September 2020, 100 patients with osteoporotic low back pain were recruited from outpatients of orthopedics department of the Shuguang Hospital affiliated to Shanghai University of Traditional Chinese Medicine. A computer-generated random number table was utilized, and the resulting numbers were sequentially placed in opaque, sealed envelopes. These envelopes were then distributed in accordance with the recruitment order of enrolled patients, randomly assigning patients to either the treatment or control group in a 1:1 ratio based on the order of randomization within the envelopes. All patients provided informed consent, and the trial received approval from the Ethics Committee of Shuguang Hospital affiliated with Shanghai University of Traditional Chinese Medicine (Approval No. 2019–722-77-01) and was registered in the Chinese Clinical Trial Registry (Registration No. ChiCTR1900025464).

Inclusion Criteria

The inclusion criteria were as follows: (a) postmenopausal women aged between 45 and 75 years, with at least one year since menopause; (b) dual-energy X-ray bone density below 2.5 standard deviations from the normal value; (c) moderate low back pain persisting for more than three months and with a Visual Analog Scale (VAS) pain score of ≥ 3;[6] (d) patients with the ability to provide informed consent and willingly sign the informed consent form.

Exclusion Criteria

The exclusion criteria were as follows: (a) use of other medications that may affect bone metabolism; (b) lumbar vertebral compression fractures; (c) lumbar disc herniation, spondylolisthesis, or spinal stenosis; (d) severe underlying conditions that may impact treatment; (e)participation in other clinical trials in the past month; (f) known allergy to the study drug.

Trial Interventions

The control group was administered 600 mg of Caltrate D once daily after meals, with one tablet per dose, for a duration of 48 weeks. Caltrate D, manufactured by Wyeth Pharmaceuticals Co. LTD, contained 600 mg of calcium and 125 IU of vitamin D3 per tablet (Approval No. H10950029). In addition to Caltrate D, the treatment group received Migu capsules (3 capsules per dose, three times a day) for the same 48-week period. Migu capsules, produced by Shuguang Hospital (Approval No. Z04100615), consisted of the following ingredients: *Epimedii Folium, Polygoni Multiflori Radix, Astragali Radix, Dendrobii Caulis, Cistanches Herba, Drynariae Rhizoma, and Chrysanthemi Flos.*

Outcomes

Apart from bone density measurements taken at baseline, weeks 24 and 48, other outcomes were assessed at baseline, 12 weeks, 24 weeks, 36 weeks, and 48 weeks after enrollment. The primary outcome was the low back pain intensity score on the visual analogue scale at 24 weeks after randomization. The Visual Analog Scale (VAS) comprises a 10 cm line segment with anchor points at each end. Participants were instructed to mark, using a vertical line, the level of low

back pain they experienced in the past 48 hours. The distance from the starting point to the vertical line was measured to determine the degree of pain. A higher numerical value indicated a greater intensity of pain.

Secondary outcomes included low back pain intensity scores on the VAS at week 48, the Roland-Morris Disability Questionnaire (RMDQ), bone mineral density (BMD), and serum bone turnover markers. The RMDQ was designed by British scholars Roland and Morris to assess the physical functioning of individuals with low back pain. The questionnaire encompasses 24 specific questions related to the impact of low back pain on both back health and overall well-being. Each question contributes one point, with higher scores indicating a more pronounced level of functional impairment.[14] BMD was measured using dual-energy X-ray absorptiometry to assess the bone density of the lumbar spine and hip in patients. The absolute values of bone density were recorded for L1 to L4 vertebrae and the femoral neck. The measurement personnel held certification from the International Society for Clinical Densitometry. Bone turnover markers, including osteocalcin, parathyroid hormone, β isomer of C-terminal telopeptide of type I collagen (β-CTX), and vitamin D, were measured in the clinical laboratory of Shuguang Hospital.

Adverse Events

All patients underwent liver function (alanine aminotransferase, aspartate aminotransferase), kidney function (uric acid and blood urea nitrogen), and electrolyte checks at baseline, as well as after 12 and 24 weeks of treatment initiation. Any adverse events occurring during the treatment period were documented to assess the safety of the treatment.

Sample Size

This randomized controlled trial was designed as a superiority trial. The treatment group receives Migu capsules in addition to Caltrate D, while the control group receives Caltrate D alone. The primary outcome was the low back pain intensity score on the Visual Analog Scale at 24 weeks post-randomization. Based on the literature review,[15] the observed difference between the treatment and control groups was −3, with a standard deviation of 1.27. Setting a two-sided α of 0.05 (one-sided 0.025) and a power (1-β) of 0.95, with a minimum clinically significant difference of 2,[16] and a sample size ratio of 1:1 between the experimental and control groups, following the method by Chow et al,[17] the sample size for the treatment group was calculated to be 43 cases, and for the control group, it was also 43 cases. Considering a 15% attrition rate due to loss to follow-up or refusal, the final required sample size is at least 50 cases in the experimental group and 50 cases in the control group, totaling an inclusion of 100 cases in the study.

Statistical Analysis

All the analyses were performed according to the intention-to-treat principle with SPSS software, version 26. *P* values less than 0.05 were considered statistically significant and tests were 2-sided. Continuous baseline characteristics are represented as median (P_{25}-P_{75}) or mean ± standard deviation, while categorical variables are expressed as frequencies. For intergroup analysis, independent sample *t*-tests are employed for data that adhere to a normal distribution, while the Wilcoxon rank-sum test is utilized for skewed distribution of measurement data.

The primary outcome was reported by the adjusted mean difference of the two groups at week 24 and evaluated by a mixed model of longitudinal regression for repeated measures. A compound symmetry covariance matrix was used to model the within-patient variance–covariance errors. Fixed effects were the low back pain score at baseline, the treatment groups, the postoperative visits, and the treatment by visit interaction. The low back pain score at baseline was also included as a covariate. The patient was included in the model as a random effect. Similar analyses were conducted for the secondary outcomes with pairwise comparisons between groups at 12 weeks, 24 weeks, 36 weeks and 48 weeks.

Results

Baseline Characteristics

After an initial screening of 112 individuals, 12 were excluded due to refusal to be grouped or not meeting the inclusion criteria. Ultimately, 100 individuals were randomly assigned to treatment and control groups, with each group consisting of 50 individuals, as illustrated in Figure 1. The mean baseline age was 65.48±8.34 in the treatment group and 66.87

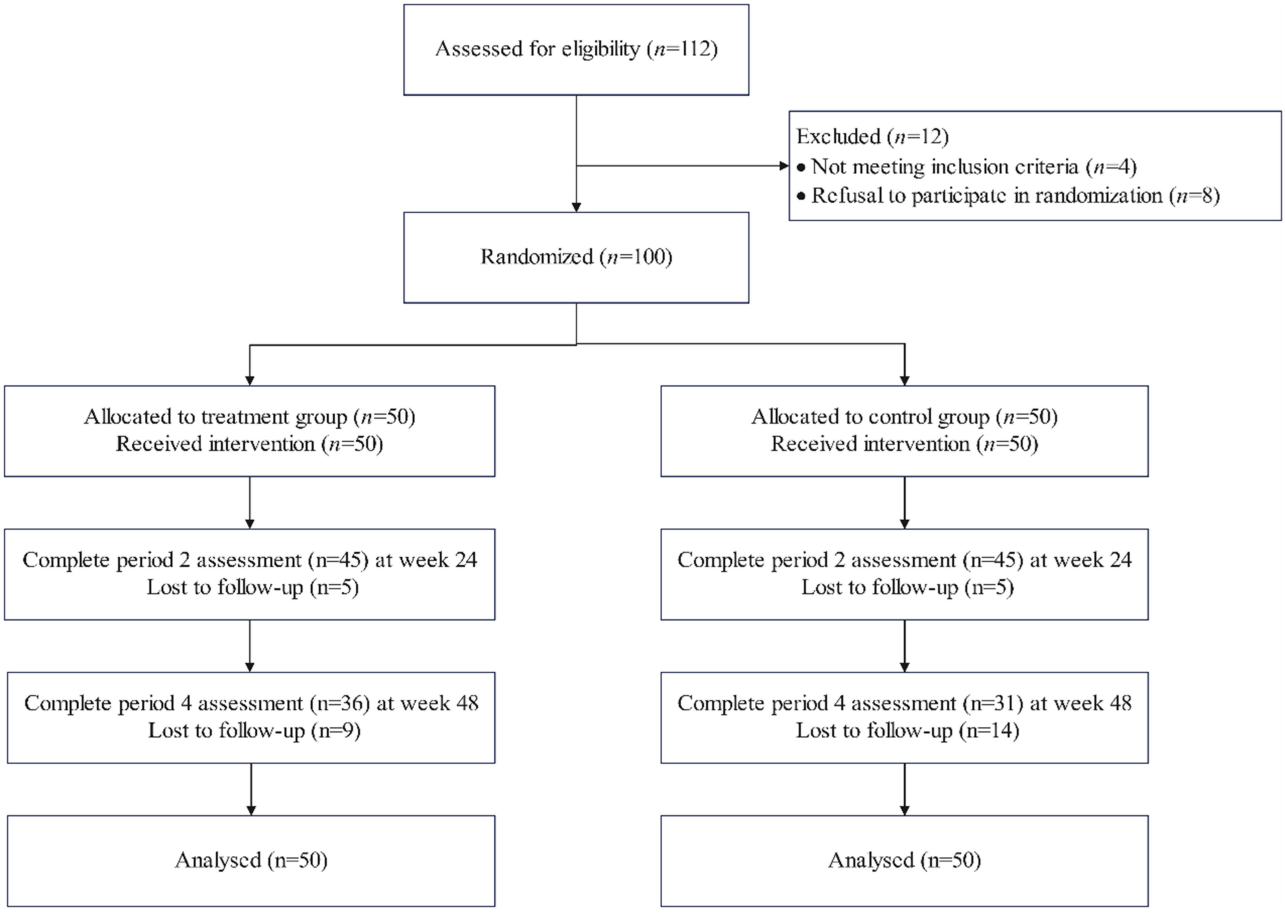

Figure 1 Flowchart of participants in the randomized controlled trial.

±8.47 in the control group. The mean baseline pain intensity scores for low back pain in the treatment group and the control group were 6.18 ± 1.67 and 6.10 ± 1.73, respectively. The mean baseline RMDQ scores for in the treatment group and the control group were 7.52±3.82 and 6.10 ± 1.73, respectively. There were no statistically significant differences in general characteristics, including age, low back pain scores, RMDQ scores, serum bone metabolism markers, and bone density, between the two groups of patients, as shown in Table 1.

Primary Outcomes

At 24 weeks, the score of low back pain intensity was 2.881±0.150 in treatment group and 4.703±0.161 in the control group (Table 2). The mean difference between the two groups was −1.822 (95%confidence interval [CI], −2.255 to −1.388, P<0.001), suggesting that the combination of Migu Capsules with Caltrate D was more effective in alleviating osteoporotic low back pain compared to the singular use of Caltrate D. However, this difference did not reach the expected minimum clinically important difference. Despite this, both groups showed an alleviation of low back pain at 24 weeks when compared to their respective baseline (difference, 3.278; 95% CI, 2.754 to 3.802; P<0.001 in treatment group; 1.423; 95% CI, 0.858 to 1.987; P<0.001 in control group), as shown in Figure 2A.

Secondary Outcomes

At 48 weeks, the score of low back pain intensity was 1.561±0.150 in treatment group and 3.219±0.161 in the control group (Table 2). Although there was a statistically significant difference in pain improvement between the intervention group and the control group (difference, −1.657; 95% CI, −2.091 to −1.224, P<0.001), this difference still did not reach the expected minimum clinically important difference, as shown in Figure 2A.

Table 1 Demographic and Clinical Characteristics of the Patients at Baseline

Characteristic	Treatment Group (N=50)	Control Group (N=50)	*P* Value
Age(years)	65.48±8.34	66.87±8.47	0.554
Weight(kg)	54.97±7.85	56.10±7.93	0.563
Height(cm)	156.58±4.98	155.84±4.98	0.544
BMI (kg/cm^2)	22.45±3.20	23.16±3.61	0.387
Low back pain VAS (score)	6.18±1.67	6.10±1.73	0.847
RMDQ (score)	7.52±3.82	6.54±3.36	0.274
Bone turnover markers			
Osteocalcin (ng/mL)	14.81±5.99	15.21±6.74	0.435
Parathyroid hormone (pg/mL)	35.26±17.77	40.67±20.33	0.241
β-CTX (ng/mL)	0.25±0.18	0.21±0.12	0.306
Vitamin D (ng/mL)	27.14±8.95	23.67±8.74	0.210
Bone mineral density			
L1 (g/cm^2)	0.806±0.082	0.778±0.085	0.307
L2 (g/cm^2)	0.844±0.112	0.841±0.104	0.975
L3 (g/cm^2)	0.919±0.111	0.904±0.120	0.531
L4 (g/cm^2)	0.932±0.137	0.941±0.129	0.837
Femoral neck (g/cm^2)	0.726±0.091	0.717±0.074	0.720

Notes: Values are mean ± SD. There was no difference among the two groups.
Abbreviations: VAS, Visual Analogue Scale; RMDQ, Roland-Morris Disability Questionnaire; β-CTX, β-Crosslaps.

Table 2 Primary and Secondary Outcomes

Outcome	Treatment Group		Control Group		Mean Difference (95% CI)
	No. of Patients	Value	No. of Patients	Value	
Primary outcome					
VAS score for low back pain at 24 weeks	45	2.881±0.121	45	4.703±0.121	−1.822(−2.255 to −1.388)[a]
Secondary outcomes					
VAS score for low back pain at 48 weeks	36	1.561±0.131	31	3.219±0.138	−1.657(−2.091 to −1.224)[a]
Roland-Morris Disability Questionnaire score					
At 24 weeks	45	2.406±0.223	45	4.173±0.2224	−1.767(−2.517 to −1.017)[a]
At 48 weeks	36	0.851±0.243	31	2.722±0.257	−1.871(−2.621 to −1.121)[a]
Bone turnover markers					
Osteocalcin (ng/mL)					
At 24 weeks	45	17.402±0.567	45	15.411±0.567	−1.991(−4.136 to 0.155)
At 48 weeks	36	19.314±0.644	31	16.241±0.611	−3.073(−5.219 to −0.928)[b]
Parathyroid hormone (pg/mL)					
At 24 weeks	45	34.523±1.576	45	37.357±1.578	2.834(−2.996 to 8.665)
At 48 weeks	36	33.329±1.834	31	34.932±1.720	1.603(−4.228 to 7.434)
β-CTX (ng/mL)					
At 24 weeks	45	0.212±0.013	45	0.235±0.013	0.023(−0.025 to 0.072)
At 48 weeks	36	0.166±0.015	31	0.231±0.014	0.065(0.016 to 0.114)[b]
Vitamin D (ng/mL)					
At 24 weeks	45	27.246±0.663	45	28.454±0.664	1.208(−1.133 to 3.549)
At 48 weeks	36	29.700±0.751	31	28.905±0.710	−0.795(−3.136 to 1.546)
Bone mineral density					
L1 (g/cm^2)					
At 24 weeks	45	0.813±0.005	45	0.786±0.005	−0.026(−0.048 to −0.005) [b]
At 48 weeks	36	0.847±0.006	31	0.793±0.006	−0.055(−0.076 to −0.033) [a]
L2 (g/cm^2)					
At 24 weeks	45	0.849±0.006	45	0.846±0.006	−0.003(−0.024 to 0.018)
At 48 weeks	36	0.893±0.006	31	0.855±0.006	−0.038(−0.059 to −0.017) [a]

(*Continued*)

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Table 2 (Continued).

Outcome	Treatment Group		Control Group		Mean Difference (95% CI)
	No. of Patients	Value	No. of Patients	Value	
L3 (g/cm^2)					
At 24 weeks	45	0.926±0.006	45	0.922±0.006	−0.003(−0.025 to 0.018)
At 48 weeks	36	0.991±0.006	31	0.936±0.007	−0.055(−0.076 to −0.033) [a]
L4 (g/cm^2)					
At 24 weeks	45	0.955±0.007	45	0.947±0.007	−0.008(−0.033 to 0.017)
At 48 weeks	36	1.024±0.008	31	0.964±0.008	−0.060(−0.085 to −0.035) [a]
Femoral neck (g/cm^2)					
At 24 weeks	45	0.726±0.003	45	0.725±0.003	−0.001(−0.011 to 0.008)
At 48 weeks	36	0.757±0.003	31	0.734±0.003	−0.023(−0.033 to −0.014) [a]

Note: Plus–minus values are means ± SE. Means are derived from mixed-model repeated-measures analysis. Control group: Caltrate D 600 mg, one tablet per dose, once daily for 48 weeks. Treatment group: Caltrate D 600 mg, one tablet per dose, once daily for 48 weeks and Migu capsules, 3 capsules per dose, three times a day for 48 weeks. [a]*P*<0.001 for the between-group difference. [b]*P*<0.05 for the between-group difference.
Abbreviations: CI, confidence interval; β-CTX, β isomer of C-terminal telopeptide of type I collagen.

Considering the impact of osteoporotic low back pain on lumbar function, the addition of Migu capsules proved to be more effective in reducing the RMDQ score compared to the sole use of Caltrate D. This observation held true for both the 24-week and 48-week follow-up periods (difference, −1.767; 95% CI, −2.517 to −1.017, at 24 weeks; −1.871,95% CI, −2.621 to −1.121, at 48 weeks, respectively), as shown in Table 2 and Figure 2B.

The additional intake of Migu capsules by patients lead to varying changes in four bone turnover indicators, as shown in Table 2 and Figure 2C–F. For osteocalcin, the difference between the treatment group and the control group at 24 weeks was not statistically significant (P=0.069). It was only after 36 weeks that the impact of additional intake of Migu capsules on osteocalcin became evident (difference, 2.452; 95% CI, 0.306 to 4.598; P=0.025). Similar to Osteocalcin, the bone turnover marker β-CTX also manifested differences that become apparent only after an extended observation period, specifically after 36 weeks (difference, −0.049; 95% CI, −0.097 to 0.0001; P=0.049). For both parathyroid hormone and Vitamin D, there was no statistically significant interaction between group and follow-up time (all P > 0.05). Additionally, there was no statistically significant difference between groups for these two indicators (all P > 0.05).

In general, continuous administration of Migu capsules for at least 48 weeks was required to obtain benefits in bone density compared to the use of Caltrate D alone. This applied to both the lumbar region and the femoral neck, as shown in Table 2 and Figure 2G–K.

Safety Evaluation

Among the two groups, three cases in the treatment group experienced oral ulcers after taking Migu capsules. The symptoms were alleviated with the use of heat-clearing traditional Chinese medicines. In the control group, two cases exhibited elevated alanine transaminase levels during the treatment period due to acute gastrointestinal inflammation. Following antibiotic treatment, their liver function returned to normal, and there have been no abnormalities in liver function during follow-up. No other adverse events were reported in either group.

Discussion

In our single center randomized controlled trial involving patients with osteoporotic lower back pain, the co-administration of Caltrate D with Migu capsules for a continuous duration of 24 weeks was found to alleviate lower back pain. Previous studies have indicated that bisphosphonates,[2] denosumab,[3] and teriparatide[4] can significantly alleviate lumbar pain in patients with osteoporosis, albeit potentially accompanied by certain trade-offs, such as gastroesophageal irritation.[18] However, research on Traditional Chinese Medicine interventions for this patient population was relatively scarce. In a study where heat-sensitive moxibustion was combined with conventional Western medicine for a duration of 8 weeks, improvements were observed in the severity of low back pain in patients with osteoporosis.[19] Previous randomized controlled trials have also suggested that intervention using the “benefit qi and

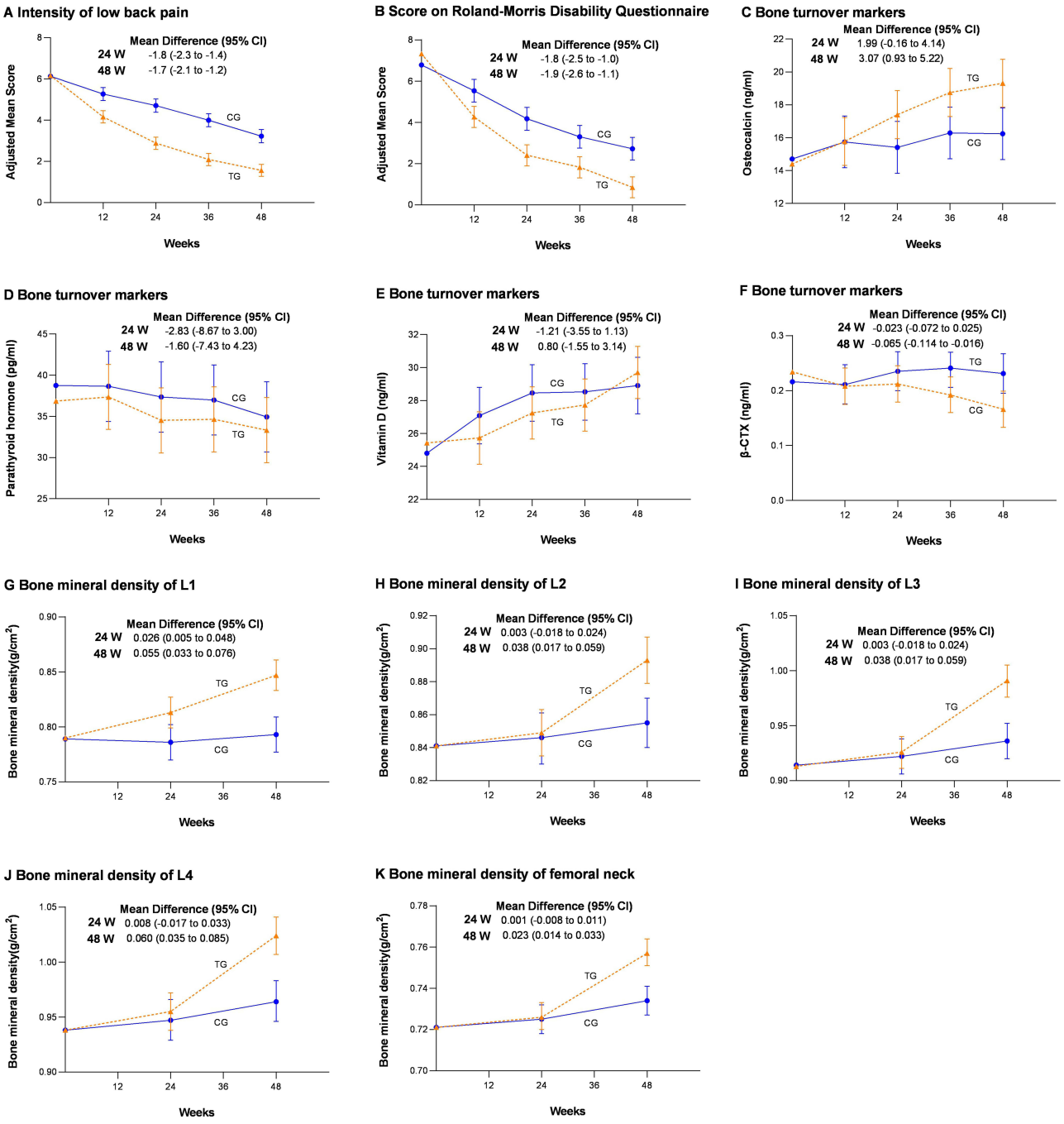

Figure 2 Primary and Secondary Outcomes at Each Follow-up Visit through 48 weeks.

Notes: The mean differences were derived from a longitudinal regression mixed model for repeated measures. The subfigures represent the differences between the intervention and control groups over various time periods, as outlined below: Figure A shows the intensity of low back pain, Figure B displays Roland-Morris Disability Questionnairs scores, Figures C through F depict bone turnover markers (Osteocalcin, Parathyroid hormone, Vitamin D, and β-CTX), and Figures G through K illustrate bone mineral density measurements at L1-L4 and the femoral neck. The solid blue line represents the control group (CG), while the dashed orange line represents the treatment group (TG).

Abbreviations: CI, confidence interval; β-CTX, β isomer of C-terminal telopeptide of type I collagen; 24W, 24th week;48W, 48th week.

tonify kidney yin and yang" approach for a period of 6 months can alleviate pain.[11] Our study aligns with previous conclusions, demonstrating the efficacy of traditional Chinese medicine formulations in relieving pain. Furthermore, a notable advantage of our research was the consideration, from its inception, of whether the alleviation of pain could

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reach the minimal clinically important difference. The results indicated that while additional intake of Migu capsules can relieve pain, the extent of pain relief did not reach the minimum clinically important difference.

The International Association for the Study of Pain (IASP) defines chronic pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage".[20] Pain is considered an enhanced awareness feedback and can be viewed as a result of widespread neural network output in the brain rather than a direct impact of sensory input caused by damage.[21] Osteoporosis can give rise to certain types of pain, categorizable into two types: traumatic pain caused by fragility fractures due to compromised bone integrity, and pain resulting from the pathological aspects of osteoporosis without evidence of fractures.[22] The characteristics of osteoporotic pain include sensory features arising from changes, fractures, and muscle atrophy, as well as nociceptive and neuropathic pain. Osteoporotic pain may be associated with osteoclast activity and central sensitization.[23] In a healthy skeletal system, the activities of osteoblasts and osteoclasts, regulated by bone-derived factors, hormones, and cytokines, are in dynamic equilibrium.[24] Elevated levels of bone resorption impact the pathological changes in bone sensory nerve fibers, enhancing osteoclast activity. Overexpression of nociceptors leads to the occurrence of pain.[25] With age, bone mass decreases, but sensory nerve fibers do not decrease in proportion, resulting in an increased relative density and contributing to the mechanism of osteoporotic pain.[26]

As a component of Migu capsules, *Epimedii Folium* can serve as an adjunctive or alternative treatment, reducing pain while improving bone mineral density and therapeutic outcomes.[27] The underlying mechanism may involve the regulation of osteogenic activity mediated by Runx-2 in mesenchymal stem cells, as well as the adipogenesis processes associated with PPAR-γ, which could potentially contribute to the improvement of bone health.[28] *Polygoni Multiflori Radix* regulates bone metabolism by promoting osteoblast activity and inhibiting osteoclast activity. It has low toxicity and minimal adverse effects, providing relief from osteoporotic pain.[29] Additionally, evidence supports the role of Vitamin B1 and Vitamin B2 in improving bone tissue structure and addressing imbalances in bone metabolism, leading to a significant increase in bone density. *Astragali Radix* can alleviate osteoporosis by elevating overall bone mineral density levels, improving the bone volume-to-total volume ratio, and inhibiting the degradation of trabecular bone.[30,31]

These findings may elucidate the reasons behind the efficacy of traditional Chinese medicine components in Migu capsules for improving osteoporotic pain.

Patients' preferences and expectations for different treatment options for the same condition can enhance the perceived efficacy of interventions.[32] A secondary analysis of a randomized controlled trial on chronic low back pain found that individuals expecting pain relief from yoga were more likely to experience positive outcomes, particularly when assigned to the yoga group.[33] Thus, in managing chronic low back pain, physicians should engage in shared decision-making with patients, selecting the most suitable treatment based on patient preferences, feasibility, and the risks and costs associated with each intervention.[34] Although this study did not initially record patients' expectations regarding Chinese medicine treatment, the recruitment of all participants from outpatient clinics at this traditional Chinese medicine hospital suggests a preference among patients for Chinese medicine in managing osteoporotic low back pain.

Furthermore, growing evidence suggests that resistance training and exercise provide moderate clinical benefits for pain control in nonspecific chronic low back pain in short term.[35–39] However, for the population examined in this study—patients with osteoporotic low back pain, a subgroup experiencing both osteoporosis and low back pain—it is crucial for treatment providers to consider primary endpoints for osteoporosis when prescribing exercise regimens and performing manual therapies. Efforts should prioritize both maintaining bone density and alleviating symptoms, such as pain reduction and functional improvement. Further evidence is needed to substantiate these approaches. This study has certain limitations. Firstly, the numerical value used as the minimal clinically important difference was based on a generic indicator for low back pain, and future research should consider defining corresponding values specifically for osteoporotic lower back pain. Secondly, the study did not evaluate the efficacy of Migu capsules based on fracture endpoints. Thirdly, despite the presence of *Epimedii Folium* in Migu capsules, we did not conduct safety assessments specifically targeting estrogen-sensitive organs and estrogen serum indicators.

Clinical Implications

The results of this single-center randomized controlled trial indicate that, in postmenopausal women with osteoporotic low back pain, the addition of Migu capsules to continuous Caltrate D supplementation effectively alleviates pain by the 24th week. In terms of bone density benefits, however, the additional use of Migu capsules shows significant effects compared to Caltrate D alone only by the 48th week. These findings provide scientific evidence supporting the clinical application of Migu capsules.

Conclusion

In conclusion, in postmenopausal women with osteoporotic lower back pain aged 45 and above, the combined use of Migu capsules with Caltrate D confer additional benefits in pain relief compared to the sole use of Caltrate D. To achieve a certain degree of bone density difference, at least an additional continuous intake of Migu capsules for 48 weeks was required when compared to the use of Caltrate D alone.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 helsinki declaration and its later amendments or comparable ethical standards. The Ethics Committee of Shuguang Hospital affiliated with Shanghai University of Traditional Chinese Medicine (Approval No. 2019-722-77-01).

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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